PRESS RELEASE

CLINICAL DATA FROM MERZ NEUROSCIENCES' PHASE III EXTENSION STUDY OF XEOMIN (incobotulinumtoxinA) FOR SPASTICITY TO BE PRESENTED AT 2015 AAPM&R ANNUAL MEETING

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RALEIGH, N.C. – OCTOBER 2, 2015 – BUSINESS WIRE – Merz Neurosciences, a division of Merz North America (U.S. affiliate of the global Merz Pharma Group), today announced that data from the open-label extension of its pivotal Phase 3 clinical trial in upper limb spasticity will be presented during the Annual Assembly of the American Academy of Physical Medicine & Rehabilitation (AAPM&R), held October 1-4, 2015 in Boston, MA. Merz has submitted an sBLA to the FDA to seek approval for the use of incobotulinumtoxinA in the treatment of upper limb spasticity.

"We look forward to sharing data from the open label extension of our pivotal Phase 3 clinical trial in upper-limb spasticity with the attendees of this year's AAPM&R Annual Meeting," said Bill Humphries, President and Chief Executive Officer, Merz North America, Inc. "Motivated by the mission of delivering a better experience for individuals living with movement disorders, Merz is proud to support ongoing investment in large, well-controlled clinical trials that are focused on neurotoxin therapy."

An abstract titled "Efficacy and safety of repeated incobotulinumtoxinA injections for upper-limb post-stroke spasticity" has been accepted by AAPM&R in the Neurological Rehabilitation category as Poster #54 and will be presented on Friday, October 2, 2015 from 12:00 PM - 1:00 PM EDT in Exhibit Hall B, on the Plaza Level of the Hynes Convention Center. The presenting author will be Dr. Michael Munin, MD, co-investigator and professor and vice chair of Clinical Program Development in the Department of Physical Medicine and Rehabilitation at the University of Pittsburgh School of Medicine.

"Open-label extension studies such as the PURE OLEX ensure that treatments are continually evaluated in order to monitor the long-term safety and efficacy of neurotoxin therapy," said Dr. Michael Munin. "Ongoing research is critical in expanding the level of evidence and experience for physicians using botulinum toxin in the treatment of upper-limb spasticity."

This abstract has been published in the September 2015 supplement of "Physical Medicine & Rehabilitation," the scientific journal of the AAPM&R. A preview of the abstract is available at this link.

About PURE OLEX

PURE OLEX (**P**ost-stroke Spasticity **U**ppe**R** Limb Study to Investigate **E**fficacy and Safety of NT 201 clinical trial for incobotulinumtoxinA) was a prospective, 36-week open-label extension (OLEX) of a randomized, double-blind, placebo-

controlled Phase 3 trial (NCT01392300) to investigate efficacy and safety of repeated incobotulinumtoxinA injections for upper-limb spasticity. Participants were subjects (n=248) with upper limb post-stroke spasticity, who completed the 12-week double-blind main period (MP). In this open-label extension, subjects received three treatments with incobotulinumtoxinA (400 U) injected into the affected muscles of one selected upper-limb at fixed 12-week injection intervals. Main outcome measures included evaluation of muscle tone (Ashworth Scale), Disability Assessment Scale (DAS), Carer Burden Scale, and incidence of adverse events. As seen in the MP, subjects with an improvement of ≥1 on the Ashworth Scale at Week 4 were classified as responders and showed significant improvements in disability associated with spasticity ($p<0.0001$). Further, the mean DAS score significantly improved from each incobotulinumtoxinA treatment to the respective 4-week assessment ($p<0.0001$ for all). Three percent of subjects experienced an adverse event; the most common being pain in the extremity and constipation (n=2, 0.7%). No serious treatment-related adverse events were reported.

About Merz Neurosciences

Merz Neurosciences is a division of Merz North America, a specialty healthcare company that develops and commercializes treatment solutions in aesthetics, dermatology and neurosciences in the U.S. and Canada. Merz Neurosciences is committed to providing high-quality products and outstanding service to physicians in the fields of neurology, physiatry and otolaryngology. By developing products that improve patients' health and help them to live better, feel better and look better, Merz will continue to make significant contributions to the well-being of individuals around the world. Merz Neurosciences is an important contributor to the U.S. neurosciences space, offering a well-balanced product portfolio that includes the neurotoxin Xeomin® (incobotulinumtoxinA), the anticholinergic Cuvposa™ (glycopyrrolate) Oral Solution and the Prolaryn™ family of products.

For more information about Merz Neurosciences and their U.S. product portfolio, please visit www.merzusa.com.

About Xeomin® (incobotulinumtoxinA)

INDICATIONS

XEOMIN® is a prescription medicine that is injected into muscles and used:

- **to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults.**
- **to treat abnormal spasm of the eyelids (blepharospasm) in adults who have had prior treatment with onabotulinumtoxinA (Botox®).**

IMPORTANT SAFETY INFORMATION

XEOMIN® may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems any time (hours to weeks) after treatment with XEOMIN:

- **Problems with swallowing, speaking, or breathing can happen after an injection of XEOMIN** if the muscles that you use to breathe and swallow become weak. If these problems are severe, you could die. People with certain breathing problems may need to use muscles in their neck to help them breathe and may be at greater risk for serious breathing problems with XEOMIN.
- Swallowing problems may last for several months, and during that time you may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving XEOMIN have the highest risk of getting these problems.
- **Spread of toxin effects**. In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include: loss of strength and muscle weakness all over the body, double vision, blurred vision and drooping eyelids, hoarseness or change or loss of voice, trouble saying words clearly, loss of bladder control, trouble breathing, trouble swallowing.

Do not take XEOMIN if you: are allergic to XEOMIN or any of the ingredients in XEOMIN; had an allergic reaction to any other botulinum toxin product such as rimabotulinumtoxinB (Myobloc®), onabotulinumtoxinA (Botox®, Botox® Cosmetic), or abobotulinumtoxinA (Dysport®); have a skin infection at the planned injection site.

Before you take XEOMIN, tell your doctor about all your medical conditions, including if you have a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome), as you may be at increased risk of serious side effects including difficulty swallowing or breathing. Tell your doctor if you have: had any side effect from any other botulinum toxin in the past; breathing problems such as asthma or emphysema; a history of swallowing problems or inhaling food or fluid into your lungs (aspiration); bleeding problems; drooping eyelids; plans to have surgery; had surgery on your face. Also tell your doctor if you are pregnant or plan to become pregnant (it is not known if XEOMIN can harm your unborn baby); are breastfeeding or plan to breastfeed (it is not known if XEOMIN passes into breast milk).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins and herbal products. Using XEOMIN with certain other medicines may cause serious side effects. **Do not start any new medicines until you have told your doctor that you have received XEOMIN in the past.**

Especially tell your doctor if you have received any other botulinum toxin product in the last four months or in the past. Be sure your doctor knows exactly which product you received. The dose of XEOMIN may be different from other botulinum toxin products that you have received. Tell your doctor if you: have recently received an antibiotic by injection; take muscle relaxants; take an allergy or cold medicine; take a sleep medicine; take a blood thinner medicine.

XEOMIN may cause loss of strength or general muscle weakness, blurred vision, or drooping eyelids within hours to weeks of taking **XEOMIN**. **If this happens, do not drive a car, operate machinery, or do other dangerous activities.**

XEOMIN may cause other serious side effects including allergic reactions. Symptoms of an allergic reaction to XEOMIN may include: itching, rash, redness, swelling, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing or asthma symptoms, or if you get dizzy or faint.

Other side effects of XEOMIN include: dry mouth, discomfort or pain at the injection site, tiredness, headache, neck pain, muscle weakness, and eye problems, including double vision, blurred vision, drooping eyelids, swelling of your eyelids, and dry eyes. Reduced blinking can also occur. Tell your doctor or get medical help right away if you have eye pain or irritation following treatment.

Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of XEOMIN. For more information, ask your doctor or pharmacist.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

For more information, please see XEOMIN full Prescribing Information and Medication Guide.

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